REMARKS

Reconsideration of the present application is respectfully requested.

Claim 1 has been amended and new claims 5-8 have been added to application. Support for the new claims can be found throughout the specification, for example in the paragraph beginning at page 12, line 9.

Claims 1-4 have been rejected under 35 U.S.C. 112, second paragraph as being indefinite because no definite action is described with the phrase "a step of" in (a), (b), and (c) of Claim 1 and further because "exposed" in (a) and (b) of Claim 1 was unclear as to what things (air, solvents, light, an adhesive, etc.) the layer may be exposed. Claim 1 has been amended to remove the phrases "a step of" in (a), (b), and (c) and to include "exposed to air" " in (a) and (b). As Claim 1, and dependant claims 2-4 now comply with the definiteness requirements of 35 U.S.C. 112, second paragraph, it is respectfully requested that the Examiner's rejection of claims 1-4 under 35 U.S.C. 112, second paragraph be withdrawn.

Claims 1-4 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Nogami, PreGrant Publication 2004/0137040 ("Nogami"). The Examiner has asserted that Nogami teaches, as a whole, a method for producing a multi-layered pharmaceutical composition by joining two drug containing intermediates via heat fusion. The Examiner admits that Nogami does not expressly teach heat-fusing the two drug-containing layers directly, but has concluded that it is within the purview of the skilled artisan to select a drug-containing layer base that is thermoplastic and heat-fusible and thereby to omit the adhesive layers.

This rejection is respectfully traversed for the following reasons.

Applicant's specification describes that the relatively long drying time of the adhesive forming layer found in the prior art increases the instability of the drug-containing layer.

Specifically, the present application describes at page 5 lines 1-13 the following problem with the method of Nogami.

> "However, because in the first producing method or second producing method described above the water-swellable gel-forming layer forming liquid or adhesive layer forming liquid which is painted or sprayed on the drug-containing layer seeps into the drug-containing layer and the water-swellable gel-forming layer below it, long-term heating is required to dry the water-swellable gel-forming layer forming liquid or adhesive layer forming liquid painted or sprayed on the drug-containing layer. As a result, in this first producing method or second producing method there is a risk that long-term heating will destabilize the drug in the drug-containing layer."

The presently claimed invention describes methods developed specifically to overcome disadvantages of the methods of Nogami, not only minimizing the amount of time and heat to which the drug-containing layer is exposed [and thereby mitigate instability to the drug-containing layer] but also in the time and expense to form the multi-layered agent. There is no reason for one skilled in the art to use the teachings of Nogami to obtain the present invention because Nogami is silent as to the effect of the omission of the intermediate heat-fusible layers in making a multi-layered pharmaceutical film. Applicant's assertion is described at page 7, line 9 through page 8, line 12 of the specification by the following statements.

> "In the producing method of the present invention, the first drug-containing layer of the first intermediate and the second drug-containing layer of the second intermediate are heat-fused together instead of painting or spraying and then drying a second functional layer forming liquid on a drug-containing layer or an intermediate layer formed thereon when forming a second functional layer either directly or via an intermediate layer on the other side of a drug-containing layer on one side of which a first functional layer has already been formed either directly or via an intermediate layer. The heating time required for heat-fusing the first drug-containing layer of the first intermediate with the second drug-containing layer of the second intermediate is shorter than the heating time required to dry the second functional layer forming liquid painted or sprayed on the drug-containing layer or intermediate layer formed thereon. Moreover, the heating time required to form the first drug-containing layer (drying time of first drug-containing layer forming liquid) and the heating time required to form the second drug-containing layer (drying time for second drug-containing layer forming liquid) are together shorter than the heating time required to form the one drug-containing layer of the final produced pharmaceutical composition from beginning to end. Consequently, the

> stability [emphasis added] of the drug in the first drug-containing layer and second drug-containing layer can be ensured in the producing method of the present invention."

The prior art of Nogami fails to disclose a method of making a multi-layer agent without an intermediate layer between drug-containing layers. The Examiner concludes that it would have been obvious to omit the intermediate layer containing a heat-sealing adhesive and to add the heat-sealing adhesive to the drug-containing layers. Applicant asserts that one skilled in the art would not have a reasonable expectation of success that modifying the drug-containing layer as suggested by the Examiner would not adversely affect the stability of the drug within the drug-containing layer. Nogami is silent as to the effect of heat directly on the drug-containing layer and the effect of heat-sealing adhesive additives on a drug present in the drug-containing layer. Accordingly, the teachings of Nogami do no remotely contemplate or suggest omitting the intermediate layer containing a heat-sealing adhesive and adding the heat-sealing adhesive to the drug-containing layers. *United States* v. *Adams*, 383 U.S. 39, 40 (1966); *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-41, 82 USPQ2d 1385, 1396 (2007).

As Nogami clearly fails to teach or disclose all features of the method for producing a pharmaceutical composition recited in Claim 1, the Examiner has failed to establish a *prima facie* case of obviousness. Therefore, it is respectfully requested that the rejection of claim 1, as well as dependent claims 2-4, be withdrawn.

Further Nogami fails to teach or suggest the invention described in new claims 5-8 because Nogami does not disclose vinylpyrrolidone-vinyl acetate copolymer and polyvinyl acetate as a base of a drug-containing layer nor any conditions necessary to heat-fusing in the absence of intermediate layers.

In view of the foregoing, applicants respectfully submits that this application is in condition for allowance. A timely notice to that effect is respectfully requested.

Please charge any unforeseen fees that may be due to Deposit Account No. 50-1147.

Respectfully submitted,

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